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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,112	05/25/2001	Philippe Benaroch	24190.0003	8305

23767 7590 09/23/2003

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WASHINGTON, DC 20006

EXAMINER
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VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/23/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,112

Applicant(s)

BENAROCH ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 16-31, 33-51 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15, 32, 52-56, 58 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a rule 371 continuation of PCT Serial Number PCT/FR99/02691.

Claims 48-58 were previously added.

Claim 59 is newly added.

Claims 1-59 are currently pending.

### *Election/Restrictions*

1. Applicant's election without traverse of the species "polypeptide" and the subspecies "MHC Class II molecule of the DR1 serotype" in Paper No. 15, filed July 2, 2003, is acknowledged.

Therefore, in addition to **claims 1-11, 16-31, 33-51, which stand withdrawn** pursuant to Applicant's election without traverse in paper #9, filed October 8, 2002, **claim 57 is also withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Accordingly, **claims 12-15, 32, 52-56, 58 and 59 are the subject of examination** in the present Office Action.

**In view of Applicant's amendment filed July 2, 2003, all outstanding grounds of rejection are withdrawn. The following new grounds of rejection have been applied and result in this Office Action being made NON-FINAL.**

**Applicant's remarks filed March 21, 2003 have been fully considered, but are moot in view of the new grounds of rejection.**

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12-15, 32 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuck et al (Blood (1994) 84(7):2182-2188; U on form PTO-892).

The Tuck reference teaches isolated membrane-derived vesicles that were shed from COS-1 cells and comprised recombinantly produced heterologous molecules of interest [Claim 12]. Tuck teaches that one heterologous molecule of interest in the vesicles was macrophage colony stimulating factor (M-CSF), a peptide molecule [claim 13], which is a pharmacological product [claim 14], as it exerts an affect on macrophages. Tuck also teaches that the vesicles were negatively stained for electron micrographic analysis with phosphotungstic acid (page 2183, paragraph bridging columns in particular), a second heterologous molecule of interest [claim 15], which is a chemical substance deposited directly on the vesicles in accordance with the instant specification at page 14, lines 12-24 for example. Tuck further teaches the M-CSF was membrane bound on the vesicles shed into the culture supernatant [claim 52]. Tuck also teaches a composition consisting essentially of conditioned medium comprising the M-CSF-bearing vesicles [claim 32]. While Tuck does not specifically teach that the isolated vesicles are mastocyte-derived, absent a showing to the contrary regarding specific properties not present in vesicles derived from other sources, membrane vesicles derived from mastocytes are not seen as being different from vesicles derived from other eukaryotic cell types. The instant claims are product claims drawn to the end product, the isolated vesicle, not the starting material and mastocytes merely represent a preferred starting material which are used to produce an end product which is materially indistinct from isolated vesicles produced by other eukaryotic cells. The prior art anticipated the claimed invention.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 53-56, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuck et al (Blood (1994) 84(7):2182-2188; U on form PTO-892) in view of Xu et al (Molec. Immunol. (1994) 31(10):723-731; V on form PTO-892).

Tuck has been discussed supra. Tuck further teaches that MHC Class I and Class II molecules may also be borne on membrane fragments such as isolated vesicles to effect intracellular functionality (page 2182, paragraph bridging columns in particular).

Tuck et al does not specifically teach recombinant MHC Class II molecules of the DR1 serotype. Xu teaches the recombinant expression of HLA DR1  $\alpha$  and  $\beta$  chains in COS-1 cells (see entire reference)[claims 52-56 and 58-59]. It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of Xu regarding the recombinant expression of DR1  $\alpha$  and  $\beta$  chains with the teachings of Tuck to study the interaction of vesicle-bound MHC molecules with effector CD4+ T cells. One would have been motivated to combine the references with a reasonable expectation of success based upon the showing of Xu that DR1  $\alpha$  and  $\beta$  chains can be recombinantly expressed in the same type of cells as those used in the Tuck reference and the teachings of Tuck that vesicle-bound MHC molecules may stimulate T cells in a manner similar to stimulation of T cells by direct physical contact of antigen presenting cells (page 2182, paragraph bridging columns in particular) and the suggestion that the cell surface can play a role in transmitting a signal, whether by direct cell-cell interaction or by interaction of a vesicle with the effector cell (page 2187, last paragraph in particular).

#### *Conclusion*

4. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in

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Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
September 15, 2003

*Phillip Gambel*  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
TEST CENTER 1600  
9/17/03